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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/380,086 11/29/99 PEREZ

P BET-99/0730

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HM12/1009

EXAMINER

KUBELIK, A

ART UNIT

PAPER NUMBER

1638

DATE MAILED:

*16*

10/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/380,086

Applicant(s)

PEREZ ET AL.

Examiner

Anne Kubelik

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13-18 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-16 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. As requested in Paper No. 15, filed 27 August, 2001, the amendments to the specification have been entered, as have the cancellation of claims 1-12 and the addition of new claims 13-18.
2. Newly submitted claim 17 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 17 is drawn to use of an excisable AMS gene for screening for plants with an integrated transgene. The elected invention requires male sterile plants, and thus the AMS gene must be present in the plants, not excised; plants in which the AMS gene is excised would be male-fertile. Thus, the elected invention and the group to which claim 17 belongs (the original Group III) are mutually exclusive.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 17 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Amendment***

4. The amendments to the specification obviate the objection to the disclosure detailed in the prior Office action.
  5. The cancellation of claims 1, 3 and 5 obviates the rejection of those claims under 35 U.S.C. 101 detailed in the prior Office action.
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6. The rejection of claims 1, 3 and 5 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, does not apply to current claims 13-18, and is withdrawn.

***Response to Arguments***

7. Applicant's arguments that the present disclosure is sufficient to practice the claimed invention and that the attempt to incorporate subject matter into this application by reference to WO 96/33277 is not improper are accepted.

8. The rejection of claims 1, 3 and 5 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as it would apply to claims 13-18 is WITHDRAWN in light of Applicant's arguments that the plasmids described in the specification are non-essential and are only disclosed as examples. However, if any claims are written that are drawn to the plasmids or their use, the rejection will be reinstated. Applicant's arguments that the specification provides a repeatable process for producing these plasmids requires that a researcher have access to the plasmids from which these plasmids were made.

***Claim Rejections - 35 USC § 112***

9. Claims 13-16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claims 13-16 and 18 are drawn to a method for preventing dissemination of a transgene via pollen comprising integrating the transgene in a male-sterile plant. However, nowhere in the instant specification is the method of preventing dissemination of a transgene drawn to integrating the transgene in a male-sterile plant. The specification envisions the transgene and the male-sterility gene being transformed into a plant at the same time. For example, pg 3, lines 9-14, describes the plant being rendered male sterile by insertion of a sequence comprising an artificial male sterility (AMS) gene and the transgene of interest, with the two genes being genetically linked. This genetic linkage is described as desirable to prevent recombination between the AMS gene and the transgene of interest during meiosis (pg 3, lines 26-32). The specification also describes the construction of a binary vector comprising both the AMS gene and the transgene of interest (pg 11, lines 18-32); this vector would introduce the AMS gene and the transgene of interest into the plant at the same time.

Thus, the claims as written constitute NEW MATTER.

10. Claims 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Claims 16 and 18 are indefinite in their recitation of the abbreviation "AMS." For purposes of examination, it was assumed that "AMS" referred to "artificial male sterility." Such treatment does not relieve Applicant of the responsibility to respond to this rejection.

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***Claim Rejections - 35 USC § 103***

As Applicant discusses both of the 35 USC 103 rejections present in the prior Office action together, both will be discussed together here, after the statements of the rejections.

11. Claims 13-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al in view of each of Ellstrand et al and Nyers et al, as stated in the prior Office action for claims 1, 3 and 5.

12. Claims 13-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worrall et al in view of each of Ellstrand et al and Nyers et al, as stated in the prior Office action for claims 1, 3 and 5.

Applicant's arguments filed 27 August, 2001, have been fully considered but they are not persuasive.

Applicant asserts that Ellstrand et al is a general review about the risk of transgene escape through hybridization and proposes male sterility as a method of transgene isolation, but does not disclose a method for its practice. Additionally, Applicant argues that Ellstrand et al provided no evidence that pollination suppression would be effective for controlling transgene escape.

Applicant argues that Nyers et al do not disclose any system in which a transgene would be genetically linked to an AMS gene. Applicant also argues that while both Paul et al and Worrall et al teach a gene system for achieving nuclear male sterility, neither teaches the use of such a system to prevent transgene dissemination. Applicant argues that these articles would not have encouraged one skilled in the art to prevent gene escape or that it would have been successful at the time the invention was made. Applicant argues that the articles constitute at most a suggestion to try the method.

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This is not found persuasive because Worrall et al teach that transformed plants were generated that produce no pollen grains and this trait was passed along to their progeny after fertilization with wild-type pollen (pg 761, right column, paragraph 1-2). Paul et al teach tobacco plants that were completely male sterile and did not produce pollen or tapetal cells (pg 617, , paragraph spanning the columns). As the concern of Ellstrand et al was escape of transgene via pollen, and as both Paul et al and Worrall et al teach transgenic male sterile plants that produce no pollen, success was guaranteed.

Applicant presented no data to support assertions that there was a reasonable expectation that the methods of Paul et al and Worrall et al would not prevent transgene dissemination. There is none. There is no unpredictability in either the production of male sterile plants or in the introduction of a transgene, and there is no evidence in the art of a deleterious interaction between the two. It is noted also that only a reasonable expectation of success is required for determinations of obviousness, as taught in *In re O'Farrell*, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988).

The rejections hold for the claims as currently written because it is well-known in the art that the choice of whether to introduce two desired transgenes sequentially, as claimed in the instant invention, or simultaneously is an obvious design choice.

Lastly, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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13. Claims 13-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al (US Patent 5,728,558, filed July, 1990) in view of each of Ellstrand et al and Nyers et al.

The claims are drawn to a method for preventing transgene dissemination via pollen by integrating a transgene into a male sterile plant.

Fabijanski et al teach a method of producing male sterile plants and sequential transformation of those plants with another transgene or crossing those male-sterile plants with another plant that has been transformed with a transgene (column 25, lines 20-39). Fabijanski et al do not teach the use of those plants to avoid transgene dissemination.

Ellstrand et al teach that genetically engineered male sterility can be used to prevent release of engineered genes (paragraph spanning pg 440-441).

Nyers et al that genetic sterility would prevent entry of introduced genes into wild tree populations.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use the nuclear male-sterility system described in Fabijanski et al and to modify that to avoid dissemination of transgenes as taught by each of Ellstrand et al and Nyers et al. One of ordinary skill in the art would have been motivated to do so because of the risks associated with transfer of transgenes to weeds and wild plants (Ellstrand et al, pg 438, and Nyers et al).

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*Conclusion*

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached on Monday through Friday, 8:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne R. Kubelik, Ph.D.  
October 3, 2001

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

